COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15-IX-2005
C(2005) 3579

COMMISSION DECISION

of 15-IX-2005

amending, under Article 18 of Council Regulation (EEC) No 2309/93, the marketing autorisation, granted by Decision C(2004)3160, for "Ariclaim - duloxetine hydrochloride" a medicinal product for human use

ONLY THE GERMAN TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(2) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 June 2005,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4 (5) and the first subparagraph of Article 5 (7) thereof,

Having regard to the notifications submitted by Boehringer Ingelheim International GmbH under Article 4(1) and Article 5(1) of Regulation (EC) No 1085/2003,

Whereas:

(1) The placing on the market of the medicinal product "Ariclaim - duloxetine hydrochloride", which is entered in the Community register of medicinal products under the numbers EU/1/04/283/001-007 was authorised by Commission Decision C(2004)3160 of 11 August 2004.

(2) Pursuant to Article 18 (1) of Regulation (EEC) No 2309/93, the Commission requested the opinion of the Committee on Medicinal Products for Human Use as to whether, in the case of “Ariclaim - duloxetine hydrochloride” one of the measures referred to in Title XI of Directive 2001/83/EC of the European

[1] OJ L 214, 24.8.1993, p. 1 Regulation as last amended by [Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19)].
[2] OJ L 159, 27.6.2003, p. 24.

Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] should be applied.

(3) The scientific assessment by the Committee, the conclusions of which are set out in the Annex IV to this Decision, has shown that a Decision should be adopted amending the marketing authorisation for the medicinal product concerned.

(4) Decision C(2004)3160 should therefore be amended accordingly.

(5) Between 28 April 2005 and 23 June 2005, the European Medicines Agency acknowledged the validity of the type IA notification(s) and accepted the type IB variation(s) submitted. It informed the marketing authorisation holder accordingly and prepared a list of the notification(s). The variation(s) took effect from the date of the communication of the acknowledgement of validity or acceptance by the European Medicines Agency / within 30 days of the date of acknowledgement, by the European Medicines Agency, of receipt of the valid notification(s).

(6) The marketing authorisation should be updated, and Decision C(2004)3160 amended accordingly.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

(8) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3160 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2004)3160 of 11 August 2004 for the medicinal product “Ariclaim - duloxetine hydrochloride” is amended, on the basis of the scientific conclusions set out in the Annex IV to this Decision.

Article 2

Decision C(2004)3160 is amended as follows:

1) The list of notifications for minor variations submitted between 28 April 2005 and 23 June 2005 is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/552/IA/004	41.a.1 (IA) (EU/1/04/283/007)

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34)].

EMEA/H/C/552/IB/005 42.a.1 (IB) (EU/1/04/283/001-007)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

4) The following number is added to Article 1 and entered in the Community register of medicinal products:

EU/1/04/283/007 Ariclaim-20 mg-Capsule, hard, gastro-resistant-Oral use-blister (PVC/PE/PCTFE/alu)-28 capsules

Article 3

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 15-IX-2005

For the Commission
Günter VERHEUGEN
Member of the Commission